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TITLE: Comparing Web, Group and Telehealth Formats of a
Military Parenting Program

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CONTRACTING ORGANIZATION: Regents of the University of Minnesota
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14. ABSTRACT By December of 2012 approximately 2.2 million US military personnel will have served one or more times in Iraq or Afghanistan in support of Operations Enduring Freedom, Iraqi Freedom (OEF/OIF), and New Dawn (Institute of Medicine/IOM 2013). Stress associated with family separation, combat, and reintegration is extremely disruptive for parents and children. Returning service members and their families are particularly vulnerable during the reintegration period post-deployment. Risks include increases in stress, anxiety and depression, PTSD, and substance use and abuse. These outcomes lead to disruptions in interactions between parents, children, and spouses, increasing risk for children's emotional, behavior problems, and substance use. The overarching goal of our study is to address existing gaps and identified National Guard Reserve (NGR) needs that will inform the portability and access of NGR families to evidence-based programs by conducting a three-group, two-site randomized trial to test the comparative effectiveness of three ADAPT delivery approaches for 360 reintegrating NGR families randomly assigned to: (i) ADAPT group-based; (ii) ADAPT individualized web-facilitated; or (iii) ADAPT self-directed online. Families will complete pre-intervention baseline (BL) assessment (pre-test) and three post-test assessments at 6, 12- and 24 months. We hypothesize that NGR families in both the ADAPT group-based condition and the ADAPT individualized web-facilitated condition will show greater pre-post improvements in observed parenting, and parent, child, and couple functioning relative to the self-directed online condition and the ADAPT group-based condition will be equally effective as the individualized ADAPT web-facilitated condition.					
15. SUBJECT TERMS Parenting, military, comparative effectiveness, children, randomized trial, prevention					
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1. INTRODUCTION

By December of 2012 approximately 2.2 million US military personnel will have served one or more times in Iraq or Afghanistan in support of Operations Enduring Freedom, Iraqi Freedom (OEF/OIF), and New Dawn (Institute of Medicine/IOM 2013). Stress associated with family separation, combat, and reintegration is extremely disruptive for parents and children. Returning service members and their families are particularly vulnerable during the reintegration period post-deployment. Risks include increases in stress, anxiety and depression, PTSD, and substance use and abuse. These outcomes lead to disruptions in interactions between parents, children, and spouses, increasing risk for children's emotional, behavior problems, and substance use. While the need to support military families has been identified as an important national priority by numerous government-supported task forces, major gaps in effectively serving military families remain. First, most intervention and outreach efforts are guided by models lacking empirical support or programs lacking a strong theoretical background. A large majority of evaluations do not include rigorous methodology, randomization, implementation in real world settings, or long-term follow up. Second, many barriers remain for military families not living near a military competent treatment center or Veterans Administration Medical Center. The After Deployment Adaptive Parenting Tool (ADAPT) study is the only study to date with preliminary evidence from an RCT. We propose to address existing gaps and identified NGR needs that will inform the portability and access of NGR families to evidence-based programs.

Specific Aim 1: Evaluate the usability and acceptability of the individualized web-facilitated ADAPT condition with 5 military families, and an expert stakeholder panel. Compare recruitment, retention, and satisfaction with the web-facilitated condition with existing data on the ADAPT group-based and self-directed conditions.

Specific Aim 2: Conduct a three-group, two-site randomized trial to test the comparative effectiveness of three ADAPT delivery approaches for 360 reintegrating NGR families randomly assigned to: (i) ADAPT group-based; (ii) ADAPT individualized web-facilitated; or (iii) ADAPT self-directed online. Families will complete pre-intervention baseline (BL) assessment (pre-test) and three post-test assessments at 6, 12- and 24 months.

Specific Aim 3: Evaluate generalizability of ADAPT effectiveness across three intervention delivery approaches using intent to treat (ITT) analyses. We will specifically test the value-added impact of group-based delivery relative to web-facilitated and web self-directed approaches. Comparative effectiveness will be tested by specifying a non-equivalence hypothesis for group-based and web-facilitated relative to self-directed only.

- **Aim 3 Hypothesis 1.** NGR families in both the ADAPT group-based condition and the ADAPT individualized web-facilitated condition will show greater pre-post improvements in observed parenting, and parent, child, and couple functioning relative to the self-directed online condition.

Aim 3 Hypothesis 2. In testing intent to treat comparative effectiveness, the ADAPT group-based condition will be equally effective as the individualized ADAPT web-facilitated condition

2. KEY WORDS

Parenting, military, comparative effectiveness, children, randomized trial, prevention

3. ACCOMPLISHMENTS

What were the major goals of the project?

Task 1: Prepare University of Minnesota IRB and DOD regulatory documents for review and approval.

- 1a. Finalize human subjects protocol and consent documents for pilot group (N=5 families), and randomized controlled trial (N=360 families).

Task 2: Recruit for open positions (coordinator in MI and MN) and process paperwork to hire all project staff.

Task 3: Obtain U of MN IRB approval (Y1 Mos. 1-3)

Task 4: Obtain DoD HRPO approval (Y1 Mos. 1-6)

Aim 1: Examine the usability and acceptability of the delivery format for the individualized web-facilitated ADAPT:

Task 5: Systematically modify ADAPT web-facilitated delivery format in consultation with Advisory Group

- 5a. Convene expert panel (Y1 Mos. 4-5)
- 5b. Refine existing ADAPT materials (online/Google Hangout and manual) (Y1 Mos 1-10)
- 5c. Conduct pilot group to test usability (Y1 Mos. 6-9)
- 5d. Analyze pilot group data to inform materials and RCT (Y1 Mos. 9-10)
- Task 6: Train facilitator staff in MI and MN to deliver ADAPT group with fidelity (Y1 Mos 7-12)

Aim 2. Conduct a three-group, two-site randomized trial to test the comparative effectiveness of ADAPT delivery approaches.

Task 7: Recruit three cohorts of 60 families per cohort in Minnesota (20 online, 20 group, 20 web-facilitated) and 60 families per cohort in Michigan (20 online, 20 group, 20 web-facilitated) for a total of 360 families (120 per cohort). (Y1 Mos. 11-12; Y2 Mos. 13-24; Y3 Mos. 25-26)

- 7a. Obtain informed consent and complete baseline and subsequent assessments of adult adjustment, observational measures of parenting, measures of child, and couple adjustment. (Y1 Mos 11 – Y5 Mo 50)
- 7b. Randomly assign families to online ADAPT, web-facilitated ADAPT or group ADAPT; families invited to program (Cohort 1: Y1 Mos. 11-13; Cohort 2: Y2 Mos. 18-20; Cohort 3: Y2 Mos. 24 - Y3. Mo. 26)
- 7c. Assess parent satisfaction ratings via questionnaires at end of each session (Y1 Mo. 12 – Y3 Mo. 30)

Aim 3. Test the generalizability of ADAPT effectiveness across three delivery approaches using intent to treat (ITT) analyses

Task 8. Clean and analyze outcome data to examine differential effectiveness (Y2 Mo 24 – Yr 5 Mo 60)

Year 3 Quarterly Enrollment (# of families): Yr 3: Q1= 40; Q2 =35; Q3 =39; Q4 = 70

**See attached graph showing SOW Recruitment vs Actual Recruitment vs Projected Recruitment

What was accomplished under these goals?

Task 6: Second cohort of ADAPT4U facilitators were trained for in-person groups (both in MN and MI sites) on 06/26/2016 and 08/01/2016, and for telehealth on 08/16/2016.

Task 7: 302 families have consented into the study.

Other accomplishments:

- 166 families have completed their T1, baseline assessment.
- 67%* of eligible families have completed their T2 (6 month assessment).
- 85% of eligible families have completed their T3 (1 year assessment).
- 15 Oct 2016 – hired outreach consultant (retired Army Colonel) to assist with community outreach and recruitment.
- Recruitment letters were sent to MI veterans through the VA system.

*Percentage is lower than T3 due to families having to wait for their intervention to start and therefore missing their T2. Data collection at T3 is our priority and reflected in the percent completed.

What opportunities for training and professional development has the project provided?

Second cohort of ADAPT4U facilitators were trained for in-person groups (both in MN and MI sites) on 06/26/2016 and 08/01/2016, and for telehealth on 08/16/2016. Ongoing bi-weekly coaching sessions were also provided individually to trained facilitators.

How were the results disseminated to communities of interest?

Nothing to report

What do you plan to do during the next reporting period to accomplish the goals?

Our main goals for the fourth year are (1) continue recruitment for MN and MI through December 2017, (2) continue additional intervention delivery in both MN and MI through March 2018, and (3) continue data collection for T1, T2 and T2, commence data collection for T4 in August 2017.

Continue recruitment in MN and MI

- A second round of letters is being mailed to Veterans in MN through the VA.
- MI project coordinator has partnered with the MI Air National Guard to mail recruitment letters to service members who have deployed.
- We will continue heavy marketing via flyers, postcards, emails, radio spots, social media, community events and military partners. A ‘refer a friend’ campaign is currently being reviewed by our IRB. Once approved, a postcard asking current study families to ‘refer a friend’ as one method to assist with our overall recruitment. We know that word of mouth, especially among certain populations, is an effective recruitment tool.

Deliver additional interventions in MN and MI

- An additional telehealth staff member was hired to support those families waiting for intervention.
- Multiple in-person groups are scheduled to begin, in both MN and MI, late summer to early fall.

Continue data collection

- Additional assessment technicians used for data collection are being hired and trained in MI early this summer to address the turnover in staff.
- T4 (2 year assessment) protocol is being finalized and will commence in August.

4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS

Changes in approach and reasons for change

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

We continue to problem solve around Michigan's recruitment, which has been significantly slower than Minnesota's. With assistance from our outreach consultant new opportunities were developed to assist with recruitment. We expect to see and evaluate the full impact of these efforts by end of summer. Minnesota will continue to over recruit to make up the difference. In addition, Minnesota staff continue to make follow-up calls to Michigan's unresponsive families to hopefully re-engage them in study.

Changes that had a specific impact on expenditures

-Hiring of Outreach Consultant (retired Army Colonel) to support Michigan recruitment.

-Hiring of half-time telehealth facilitator to meet the intervention demands.

-Fewer facilitator hours were used in year 3 but will be used in year 4 with the delivery of more interventions to families.

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report

6. PRODUCTS**Publications, conference papers, and presentations****Journal publications**

Nothing to report

Books or other non-periodical, one-time publications

Nothing to report

Other publications, conference papers, and presentations

Nothing to report

Website(s) or other Internet site(s)

Our study website which is used for recruiting and will be used to disseminate study results is ADAPT.umn.edu

Technologies or techniques

In collaboration with a software engineer we have developed a mindfulness app to deliver practice exercises more easily than through our web portal and more specifically to carefully track usage. The app was alpha and beta tested but will not be used with subjects until IRB and HRPO approval are applied for and received (summer 2016). **UDPATE:** The mindfulness Smartphone App was approved and is currently being used by study participants.

Inventions, patent applications, and/or licenses

Nothing to report

Other products

Our study curriculum will be utilized for intervention.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Gewirtz, Abigail
Role:	PI
Person months:	2.0 months
Contribution:	Overall study oversight and strategic decision making; ensure study outcomes are achieved
Funding support:	This award
Name:	Majerle, Amy
Role:	Project Manager
Person months:	10.0 months
Contribution:	Overall management of study tasks and personnel; track study milestones; design study data collection tools
Funding support:	This award
Name:	Willer, Molly
Role:	Intervention Coordinator
Person months:	2.0 months
Contribution:	Train intervention facilitators; ensure fidelity of implementation of study interventions
Funding support:	This award plus leveraged non-sponsored funds
Name:	Tiede, Shauna
Role:	Assistant Project Manager
Person months:	11.0 months
Contribution:	Overall management of in-home assessments of participants; create study manuals; train study technicians
Funding support:	This award
Name:	Fletcher, Mark
Role:	Project Coordinator (Michigan)
Person months:	12.0 months
Contribution:	Management of study tasks for Michigan
Funding support:	This award
Name:	McCloskey, Stephen
Role:	Project Assistant (Michigan)
Person months:	6.0 months
Contribution:	Support of study tasks for Michigan; recruitment calling; scheduling of assessments; attending outreach events; general administrative duties
Funding support:	This award

Name:	Pszczola, Aneta
Role:	Assessment Technician
Person months:	12.0 months
Contribution:	Complete in-home assessment and initiate online data collection at post-intervention time points
Funding support:	This award
Name:	Crane, Bruce
Role:	Assessment Technician
Person months:	1.0 month
Contribution:	Complete in-home assessments of study participants
Funding support:	This award
Name:	Jaeger, Emily
Role:	Assessment Technician
Person months:	1.0 month
Contribution:	Complete in-home assessments of study participants
Funding support:	This award
Name:	Strub, Katy
Role:	Facilitator
Person months:	4.0 months
Contribution:	Deliver intervention to study participants
Funding support:	This award
Name:	McKeown, Jessica
Role:	Facilitator
Person months:	1.0 month
Contribution:	Deliver intervention to study participants
Funding support:	This award
Name:	Szabo, Kaitlin
Role:	Undergraduate Student Assistant
Person months:	2.0 months
Contribution:	Tracks intervention progress and subject payments, administrative tasks related to assessments
Funding support:	This award

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

GEWIRTZ, Abigail

Current Support

Title: Comparing Web, Group, and Telehealth Formats of a Military Parenting Program (PI)
[this award]

ID#: W81XWH-14-1-0143

Period: 6/1/2014 – 5/31/2019

Effort: 15%

Funding: \$821,636 for Year 4

Supporting agency & contact:

Department of Defense

Michelle Lane, michelle.d.lane9.civ@mail.mil

Goals/Specific Aims: The goal of this project is to compare the effectiveness of three different delivery formats (online, group, and telehealth) of the After Deployment Adaptive Parenting Tools (ADAPT) preventive intervention, an empirically supported parenting program for military families.

Title: SMART Optimization of a Parenting Program for Active Duty Families (PI)

ID#: W81XWH-16-1-0407

Period: 9/30/2016 – 9/29/2020

Effort: 23%

Funding: \$1,219,521/year

Supporting agency & contact:

Department of Defense

Michelle Lane, michelle.d.lane9.civ@mail.mil

Goals/Specific Aims: The objective of this study is to yield the optimal dosage, components, and sequence of a parenting program for active duty military families (ADAPT) in diverse operational tempo contexts (i.e. regular Army families and Special Operations families).

Change: This is a new active grant.

Title: The Center for Resilient Families (PI)

ID#: U79 SM080009-01

Period: 9/30/2016 – 9/29/2021

Effort: 20%

Funding: \$599,989/year

Supporting agency & contact:

DHHS SAMHSA

Maryann Robinson, maryann.robinson@samhsa.hhs.gov

Goals/Specific Aims: The Center for Resilient Families aims to raise awareness of and increase access to family interventions to promote resilience in traumatized children. The Center will reduce disparities in service access, use, and training by targeting trauma-informed family interventions to isolated families in transition: those with a parent deployed to war, Native American families on reservations, immigrant and refugee families, families involved in the juvenile justice and child welfare systems, and families in which a parent has been killed.

Change: This is a new active grant.

Recently Completed Support

Title: Midwest Continuum of Care for Child Trauma (PI)

ID#: U79 SM056177

Period: 12/30/2005 – 9/29/2016

Effort: 50%

Funding: \$399,997/year

Supporting agency & contact:

DHHS SAMHSA

Cicely Burrows-McElwain, Program Official

cicely.burrows-mcelwain@samhsa.hss.gov

Goals/Specific Aims: The goals of this project are to 1) improve access to trauma-informed practices and treatment for traumatized children and families; 2) implement and sustain evidence-based trauma treatment models in the Upper Midwest; and 3) build and maintain consensus for child trauma.

Title: Evaluation of a TF-CBT Learning Collaborative (PI)

ID#: 56797

Period: 2/7/2013 – 12/31/2016

Effort: 1%

Funding: \$42,213/year

Supporting agency & contact:

Minnesota Department of Human Services

Patricia Nygaard, pat.nygaard@state.mn.edu

Goals/Specific Aims: The purpose of this contract was to provide evaluation of training and consultation efforts to expand within the mental health provider community the clinical capacity to provide Trauma-Focused Cognitive Behavioral Therapy.

Title: Evaluation of the Sesame Street for Military Families: Transitions Program (PI)

ID#: NA

Period: 1/22/2016 – 12/31/2016

Effort: 5%

Funding: \$170,000

Supporting agency & contact:

Sesame Workshop

David Cohen, david.cohen@sesame.org

Goals/Specific Aims: The goal of this project is to assess parental and child response to the Sesame Workshop's Military Families: Transitions program.

What other organizations were involved as partners?

Organization name: University of Michigan

Location of organization: Ann Arbor, MI

Partner's contribution: Collaboration

Organization name: University of Oregon

Location of organization: Eugene, OR

Partner's contribution: Collaboration

Organization name: Implementation Sciences International, Inc.

Location of organization: Eugene, OR

Partner's contribution: Collaboration

Organization name: IRIS Media, Inc.

Location of organization: Eugene, OR

Partner's contribution: Collaboration

8. SPECIAL REPORTING REQUIREMENTS

Collaborative awards: Not applicable

Quad Chart: See attached

9. APPENDICES

Recruitment Line Graph

Comparing Web, Group, and Tele-health Formats of a Military Parenting Program

Log Number: NH13001 - EDMS 5832

W81XWH-14-1-0143



PI: Dr. Abigail Gewirtz

Org: University of Minnesota

Award Amount: \$3,051,363

Study/Product Aim(s)

Specific Aim 1: Conduct a three-group, two-site randomized trial to test the comparative effectiveness of ADAPT delivery approaches.

Specific Aim 2: Test the generalizability of ADAPT effectiveness across three delivery approaches using intent to treat (ITT) analyses.

Approach

The study will randomly allocate 360 NGR families to one of three conditions: (i) group-based web-enhanced ADAPT; (ii) individualized web-facilitated ADAPT; or (iii) self-directed web ADAPT. Families, with a child aged 5-12, will be enrolled if one parent has deployed to OEF or OIF. Families will complete a pre-intervention baseline (BL) assessment. Families will complete post-intervention follow-up assessments at 6, 12, and 24 months.

We will test the value-added impact of group-based delivery relative to facilitated and self-directed web approaches. Comparative effectiveness will be tested by specifying a non-equivalence hypothesis from group based and individualized facilitated relative to self-directed web only.



ADAPT 4 U

Preliminary results suggest that ADAPT is feasible, acceptable, and associated with improvements in parenting, couple adjustment, and emotional awareness. Thus, we have experience engaging both military parents.

Timeline and Cost

Activities	CY	14-15	15-16	16-17	17-18	18-19
Prepare IRB/DOD regulatory documents Recruit and staff open positions Modify ADAPT delivery format						
Recruit and randomize participants						
Complete baseline and subsequent participant assessments						
Conduct outcome data cleaning and analysis						
Examine differential effectiveness						
Estimated Budget (\$K)		\$255,831	\$536,315	\$749,455	\$821,636	\$688,125

Goals/Milestones

CY14 Goal –Project Preparation

- ☒ Obtained IRB/DOD approval
- ☒ Hire project staff- Staffed Key study personnel
- ☒ Modified ADAPT curriculum and delivery format
- ☒ Test ADAPT curriculum for usability- Piloted ADAPT curriculum for usability

CY15 Goal – Recruit and Randomize Participants

- ☒ Participants recruitment commenced June 18, 2015
- ☒ Commenced baseline assessment on enrolled families

CY16 Goal –Conduct Randomized Control Trial

- ☒ Deliver ADAPT group with fidelity

CY 17 Goal – Conduct Randomized Control Trial and conduct participant assessments

- ☐ Deliver ADAPT group with fidelity
- ☐ Assess adult adjustment, observational parenting, child and couple measures

CY 18 Goal - Data Cleaning and Analysis

- ☐ Create data management structure to organize, clean and analyze data

CY19 Goal – Examine differential effectiveness

- ☐ Begin outcome data cleaning and analysis

Comments/Challenges/Issues/Concerns

We continue to problem solve around Michigan's recruitment, which has been significantly slower than Minnesota's. With assistance from our outreach consultant new opportunities were developed to assist with recruitment. We expect to see and evaluate the full impact of these efforts by end of summer. Minnesota will continue to over recruit to make up the difference.

Budget Expenditure to Date

Amount spent in Y3 Q4 (03/01/17 – 05/31/17): \$179,407 total costs

Amount spent in Y3 (06/01/16 – 05/31/17): \$749,455.43 total costs

Amount spent to date (06/01/14 – 05/31/17): \$1,541,602 total costs

Updated: June 19, 2017

